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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,143	03/11/2004	Lutz Biedermann	60899 (70301)	7913
44023	7590	02/23/2006	EXAMINER	
BARLEY SNYDER PO BOX 1559 LANCASTER, PA 17608-1559			KIM, JOHN	
			ART UNIT	PAPER NUMBER
			3733	
DATE MAILED: 02/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/799,143	Applicant(s) BIEDERMANN ET AL.	
	Examiner John Kim	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
 4a) Of the above claim(s) 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/9/04, 7/27/04, 6/27/05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 10-15, and 21, drawn to anchoring element, classified in class 606, subclass 61.
- II. Claims 16, drawn to method for manufacture, classified in class 470, subclass 9.
- III. Claims 17-18 and 19-20, drawn to method to perform, classified in class 606, subclass 53.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made via a mold, rather than cutting threads on the surface.

Inventions III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case there are many different spinal fixation devices used for spinal surgery.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method of manufacture (II) and a method or performing spinal surgery (III).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- a) Figure 1 and 2
- b) Figure 3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 21 are generic for species (a) and claim 10 is generic for species (b).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mark Garscia on February 6, 2006 a provisional election was made with traverse to prosecute the invention of I (apparatus) and species (a), claims 1-9 and 21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and species.

Upon further examination, the examiner notes claim 9 recites the limitation of "polyaxial" which is not a feature in the elected species (which focuses on monoaxial). Thus, claim 9 is withdrawn from further consideration by the examiner as being drawn to a non-elected species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

A third-party submission has been filed under 37 CFR 1.99 on November 22, 2004 in the published application.

To ensure that a third-party submission does not amount to a protest or pre-grant opposition, 37 CFR 1.99 does not permit the third party to have the right to insist that the examiner consider any of the patents or publications submitted. Furthermore, if the submission or part of the submission is not in compliance with 37 CFR 1.99, that noncompliant submission or part thereof will not be entered in the application file. Therefore, unless the examiner clearly cites a patent or publication on form PTO-892, Notice of References Cited and such reference is used in a rejection or its relevance is actually discussed during prosecution, consideration by the examiner of any patent or publication submitted in a third-party submission cannot be presumed.

If the applicant wants to ensure that the information in a third-party submission is considered by the examiner, the applicant should submit the information in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98. An individual who has a duty to disclose under 37 CFR 1.56 should also submit any material information contained in a

third-party submission to the Office in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98 to ensure such material information is properly disclosed to the examiner.

Specification

The abstract of the disclosure is objected to because there are several typographical errors, for example "in to" line 6 should be "into" and there are many unnecessary periods through out the abstract. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: there are many typographical errors, for example "the receiving part comprising a U-Shaba" where it is supposed to read "U-shaped". Examiner highly suggests the applicant to proof read the application.

Appropriate correction is required.

Claim Objections

Claims 1, 4, and 7 are objected to because of the following informalities: these claims have several typographical errors, for instance in claim 1, line 7, applicant cites "red and two legs..." where red should be rod. Other typographical errors include: "ur" line 11 (removed), "front" line 14 (read as from), "find" claim 4 line 1 (read as first), "leaving" claim 4 line 2 (read as having or comprising), "Connection" claim 7 line 2 (should be lowercase). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "two legs" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 recites the limitation "the depth of the thread" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the anchoring element" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the connection" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

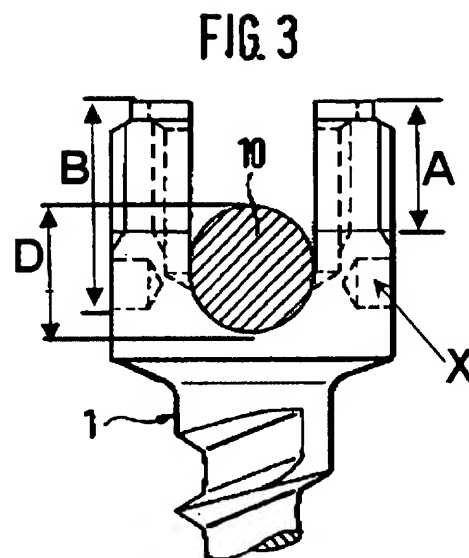
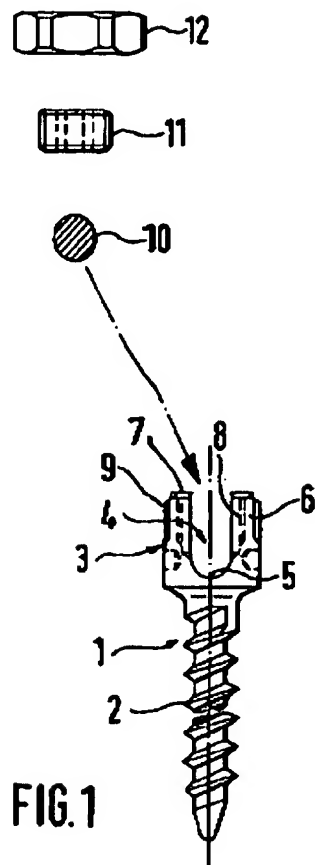
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3733

Claims 1-5, 7, 8, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harms et al. (US Pat 5873878).

Harm discloses the claimed invention, having a shaft (2), a receiving part (3) that holds a rod (10) in a channel and has two legs (6, 7) and a first thread (8 or 9), a securing element (screw member or screw nut) (11 or 12) with a second thread, and an undercut (X in modified figure below) with an edge and a distance B (claim 1, 3, 4, 5, and 21). Harm further discloses of having the invention with the undercut's depth at least the depth of the thread (claim 2), the connection between the shaft and receiving part is a monoaxial connection (claim 7), and the shaft and receiving part are an integral part (claim 8). Harm discloses the claimed invention except for having the distance A between the exterior end surface and the closest portion of the rod. It would have been an obvious matter of design choice to have a distance A, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).



Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harms et al. (US Pat 5873878) in view of Hall (US Pat 4041939).

Harm discloses the claimed invention except for having the first and second threads being either metric threads, buttress threads, flat threads or a thread with negative load-bearing angle. Hall teaches of using anchoring elements with buttress threads, which allows the element to be firmly secured to the vertebrae (col 1:51-60). It would have been obvious to one skill in the art at the time of the invention was made to make an anchoring element of Harm with buttress threads in view of Hall in order to have a firmly secured anchor element.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER